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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Randal A. Stevens, et al.	Confirmation No.	8361
Serial No.:	10/640,553	Examiner:	Mathieu D. Vargot
Filed:	August 13, 2003	Art Unit:	1791
		Docket:	136.0060001

Title: METHODS OF MAKING A NEGATIVE HEARING AID MOLD

MS Appeal Brief- Patents
Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

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Docket No.: 136.0060001

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Application No.	:	10/640,553
Applicants:	:	Randal A. Stevens
Filed:	:	August 13, 2003
TC/A.U.	:	1791
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Title		METHODS OF MAKING A NEGATIVE HEARING AID MOLD

APPEAL BRIEF

MS APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madame:

This brief is presented under 37 CFR § 41.37 in support of an appeal from a Final Office Action of February 21, 2008 regarding the above-identified application. Notice of the Appeal was filed under 37 CFR § 41.31 on May 20, 2008.

This brief is accompanied by the fee set forth in 37 CFR § 41.20(b)(2), as described in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37:

I. Real Party In Interest

II. Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

V. Summary of Claimed Subject Matter

VI. Grounds of Rejection to be Reviewed on Appeal

VII. Argument

VIII. Claims Appendix

IX. Evidence Appendix

X. Related Proceedings Appendix

The final page of this brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

In'Tech Industries, Inc., a corporation established under the laws of the State of Minnesota and having a principal place of business at 7180 Sunwood Drive, Ramsey, MN 55303, U.S.A.

II. RELATED APPEALS AND INTERFERANCES

Appellant is unaware of any related appeal or interference.

III. STATUS OF CLAIMS

A. Total Claims: 1-26

B. Current Status of Claims:

1. Claims canceled: None
2. Claims withdrawn from consideration but not canceled: 8-18 and 22-25
3. Claims pending: 1-26
4. Claims allowed: None
5. Claims rejected: 1-7, 19-21 and 26
6. Claims objected to: None

C. Claims on Appeal: 1-7, 19-21 and 26

IV. STATUS OF AMENDMENTS

No claims have been amended, cancelled, or added subsequent to the Advisory Action mailed May 7, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1

Independent claim 1 recites a method comprising: processing auditory canal dimension measurement data (lines 1-16 of paragraph 0010; line 1of paragraph 0012 through line 7 of paragraph 0013; lines 1-15 of paragraph 0030; line 1 of

paragraph 0050 through line 6 of paragraph 0051; line 1 of paragraph 0052 through line 10 of paragraph 0053; Figure 2) representing dimensions of an auditory canal (lines 1-6 of paragraph 0010; lines 1-6 of paragraph 0012; lines 1-6 of paragraph 0024; lines 1-6 of paragraph 0026; lines 1-15 of paragraph 30; line 1 of paragraph 0049 through line 8 of paragraph 0050; line 28 of paragraph 0050 through line 22 of paragraph 0052; Figure 2) to generate outside auditory canal dimension data (lines 1-6 of paragraph 0010; lines 1-6 of paragraph 0012; lines 1-6 of paragraph 0024; lines 1-6 of paragraph 0026; lines 1-15 of paragraph 30; line 24 of paragraph 0050 through line 6 of paragraph 0051; lines 1-11 of paragraph 0055; Figure 2) that represents outside dimensions of the auditory canal (lines 1-6 of paragraph 0010; lines 1-6 of paragraph 0024; lines 1-6 of paragraph 0026; lines 1-15 of paragraph 0030; line 1 of paragraph 0050 through line 22 of paragraph 0052; Figure 2);

processing the outside auditory canal dimension data (lines 1-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; lines 1-3 of paragraph 0025; lines 1-15 of paragraph 0030; line 1 of paragraph 0053 through line 5 of paragraph 0057; Figure 2) to generate outside mold data (lines 6-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; line 1 of paragraph 0017 through line 10 of paragraph 0020; line 1 of paragraph 24 through line 15 of paragraph 0030; lines 1-6 of paragraph 0038; line 1 of paragraph 0055 through line 8 of paragraph 0056; line 1 of paragraph 0057 through line 3 of paragraph 0058; lines 20-31 of paragraph 0058; Figure 2); and

creating a negative hearing aid mold (lines 1-16 of paragraph 0010; line 1 of paragraph 0017 through line 4 of paragraph 0021; line 1 of paragraph 0027 through line 15 of paragraph 0030; lines 1-3 of paragraph 0033; line 1 of paragraph 0039 through line 4 of paragraph 0040; line 1 of paragraph 0043 through line 123 of paragraph 0047; lines 1-24 of paragraph 0050; lines 1-13 of paragraph 0051; lines 1-15 of paragraph 0056; line 1 of paragraph 0058 through line 17 of paragraph 0060; Figures 2 and 7) having an inside surface (lines 8-16 of paragraph 0010; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0044; lines 1-3 and lines 11-15 of paragraph 0046; lines 7-12 of paragraph 0051; lines 20-31 of paragraph 0058; Figures 1 and 8) with dimensions the same as the outside dimensions of the auditory

canal (lines 6-15 of paragraph 0010; lines 1-15 of paragraph 0030, lines 1-13 of paragraph 0051; lines 28-31 of paragraph 0058; Figure 2), with the negative hearing aid mold suitable for receipt of a soft solid (line 1 of paragraph 0010 through line 2 of paragraph 0011; lines 1-5 of paragraph 0018; line 1of paragraph 0021 through line 3 of paragraph 0022; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0040; lines 6-8 of paragraph 0043; lines 4 of paragraph 0044 through line 15 of paragraph 0045; lines 31-33 of paragraph 0058; line 1 paragraph 0059 through line 17 of paragraph 0060; Figures 2 and 8).

Dependent Claim 2

Claim 2 is a dependent claim to independent claim 1, which recites the method of claim 1 with processing the auditory canal dimension measurement data (lines 1-16 of paragraph 0010; line 1of paragraph 0012 through line 7 of paragraph 0013; lines 1-15 of paragraph 0030; line 1 of paragraph 0050 through line 6 of paragraph 0051; line 1 of paragraph 0052 through line 10 of paragraph 0053; Figure 2) representing dimensions of the auditory canal (lines 1-6 of paragraph 0010; lines 1-6 of paragraph 0012; lines 1-6 of paragraph 0024; lines 1-6 of paragraph 0026; lines 1-15 of paragraph 30; line 1 of paragraph 0049 through line 8 of paragraph 0050; line 28 of paragraph 0050 through line 22 of paragraph 0052; Figure 2) comprising measuring the outside dimensions of an impression of the auditory canal (line 1 of paragraph 0012 through line 7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 1 of paragraph 0049 through line 22 of paragraph 0052; Figures 2 and 4) to generate the outside auditory canal dimension data (line 1 of paragraph 0012 through line 7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-6 of paragraph 0038; line 8 of paragraph 0050 through line 22 of paragraph 0052; Figures 2 and 5).

Dependent Claim 3

Claim 3 is a dependent claim to dependent claim 2, which recites the method of claim 2 with measuring the outside dimensions of the impression of an auditory

canal (line 1 of paragraph 0012 through line 7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 1 of paragraph 0049 through line 22 of paragraph 0052; Figures 2 and 4) comprising measuring the outside dimensions of the impression of the auditory canal with a laser (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 4) to generate laser measured auditory canal data (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 5).

Dependent Claim 4

Claim 4 is a dependent claim to dependent claim 2, which recites the method of claim 2 with measuring the outside dimensions of the impression of an auditory canal (line 1 of paragraph 0012 through line 7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 1 of paragraph 0049 through line 22 of paragraph 0052; Figures 2 and 4) comprising measuring the outside dimensions of the impression of the auditory canal with a laser (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 4)to generate laser measured auditory canal data (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 5); and

generating point cloud/STL data from the laser measured auditory canal data (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 1 of paragraph 0050 through line 10 of paragraph 0053; Figures 2 and 5).

Dependent Claim 5

Claim 5 is a dependent claim to dependent claim 2, which recites the method of claim 2 further comprising analyzing the impression to generate auditory canal point cloud/STL data (lines 1-6 of paragraph 0010; line 1 of paragraph 0012 through line 7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 1 of paragraph 0049 through line 22 of paragraph 0052; Figures 2 and 4)using a laser to measure a plurality of surface positions on the impression (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0036; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 4) to generate the auditory canal point cloud/STL data (lines 1-6 of paragraph 0010; lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 1 of paragraph 0050 through line 10 of paragraph 0053; Figures 2 and 5).

Dependent Claim 6

Claim 6 is a dependent claim to independent claim 1, which recites the method of claim 1 with processing the outside auditory canal dimension data (lines 1-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; lines 1-3 of paragraph 0025; lines 1-15 of paragraph 0030; line 1 of paragraph 0053 through line 5 of paragraph 0057; Figure 2) to generate outside mold data (lines 6-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; line 1 of paragraph 0017 through line 10 of paragraph 0020; line 1 of paragraph 24 through line 15 of paragraph 0030; lines 1-6 of paragraph 0038; line 1 of paragraph 0055 through line 8 of paragraph 0056; line 1 of paragraph 0057 through line 3 of paragraph 0058; lines 20-31 of paragraph 0058; Figure 2) comprising generating point cloud/STL data (lines 1-6 of paragraph 0010; lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 1 of paragraph 0050 through line 10 of paragraph 0053; Figures 2 and 5).

Dependent Claim 7

Claim 7 is a dependent claim to dependent claim 6, which recites the method of claim 6 further comprising generating stereo lithography data from the point cloud/STL data (lines 6-8 of paragraph 0010; lines 1-3 of paragraph 0015; line 1 of paragraph 0017 through line 10 of paragraph 0020; lines 1-3 of paragraph 0025; lines 1-6 of paragraph 0027; lines 1-15 of paragraph 0030; line 1of paragraph 0038 through line 4 of paragraph 0039; lines 24-33 of paragraph 0050; line 1 of paragraph 0053 through line 15 of paragraph 0056; Figure 2).

Dependent Claim 19

Claim 19 is a dependent claim to independent claim 1, which recites the method of claim 1 with processing the auditory canal dimension measurement data (lines 1-16 of paragraph 0010; line 1of paragraph 0012 through line 7 of paragraph 0013; lines 1-15 of paragraph 0030; line 1 of paragraph 0050 through line 6 of paragraph 0051; line 1 of paragraph 0052 through line 10 of paragraph 0053; Figure 2) comprising processing with a computer processor the auditory canal dimension measurement data representing dimensions of the auditory canal (lines 1-6 of paragraph; line 1 of paragraph 0050 through line 10 of paragraph 0053; Figure 2) to generate the outside auditory canal dimension data (lines 1-6 of paragraph 0024; line 24 of paragraph 0050 through line 10 of paragraph 0053; Figure 2).

Dependent Claim 20

Claim 20 is a dependent claim to independent claim 1, which recites the method of claim 1 with processing the outside auditory canal dimension data (lines 1-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; lines 1-3 of paragraph 0025; lines 1-15 of paragraph 0030; line 1 of paragraph 0053 through line 5 of paragraph 0057; Figure 2) comprises processing with a computer processor the outside auditory canal dimension data (lines 1-3 of paragraph 0025; line 1 of paragraph 0053 through line 15 of paragraph 0056; Figure 2) to generate outside mold data (lines 1-3 of paragraph 0025; line 1 of paragraph 0055 through line 15 of paragraph 0056; Figure 2).

Dependent Claim 21

Claim 21 is a dependent claim to independent claim 1, which recites the method of claim 1 further comprising measuring auditory canal dimension measurement data representing dimensions of an auditory canal directly from the auditory canal (lines 1-6 of paragraph 0026; lines 4-10 of paragraph 0049; lines 14-20 of paragraph 0052) to generate outside auditory canal dimension data (lines 1-6 of paragraph 0026; lines 4-12 of paragraph 0049; line 1 of paragraph 0050 through line 22 of paragraph 0052) that represents outside dimensions of the auditory canal (lines 1-6 of paragraph 0026; lines 4-10 of paragraph 0049; line 1 of paragraph 0050 through line 22 of paragraph 0052).

Independent Claim 26

Independent claim 26 recites a method for making a negative hearing aid mold (lines 1-5 of paragraph 0001; lines 1-15 of paragraph 0010; lines 1-3 of paragraph 0011; lines 1-6 of paragraph 0012; lines 1-7 of paragraph 0013; lines 1-4 of paragraph 14; lines 1-3 of paragraph 0015; lines 1-5 of paragraph 0016; lines 1-3 of paragraph 0017; lines 1-8 of paragraph 0019; lines 1-10 of paragraph 0020; lines 1-4 of paragraph 0021; lines 1-3 of paragraph 0022; lines 1-3 of paragraph 0023; lines 1-6 of paragraph 0024; lines 1-3 of paragraph 0025; lines 1-6 of paragraph 0026; lines 1-6 of paragraph 0027; lines 1-5 of paragraph 0028; lines 1-5 of paragraph 0029; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0033; lines 1-2 of paragraph 0034; lines 1-4 of paragraph 0036; lines 1-3 of paragraph 0037; lines 1-6 of paragraph 0038; lines 1-4 of paragraph 0039; lines 1-4 of paragraph 0040; lines 3-8 of paragraph 0043; lines 1-5 and lines 8-11of paragraph 0046; lines 1-2 of paragraph 0048; lines 4-10 of paragraph 0049; lines 10-13 of paragraph 0052) comprising the steps of:

processing laser measured auditory canal dimension measurement data (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; line 1 of paragraph 0037 through line 6 of paragraph 0038; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 4)

representing dimensions of an auditory canal (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; 1-15 of paragraph 0030; line 1 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 4) to generate outside auditory canal dimension data (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 5)that represents outside dimensions of the auditory canal (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0037; line 10 of paragraph 0049 through line 10 of paragraph 0053; Figures 2 and 5), with the laser measured auditory canal dimension measurement data obtained with a laser measurement system (lines 1-7 of paragraph 0013; lines 1-5 of paragraph 0016; lines 1-15 of paragraph 0030; line 1 of paragraph 0049 through line 10 of paragraph 0053);

processing the outside auditory canal dimension data (lines 1-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; lines 1-3 of paragraph 0025; lines 1-15 of paragraph 0030; line 1 of paragraph 0053 through line 5 of paragraph 0057; Figure 2) to generate outside mold data (lines 6-8 of paragraph 0010; lines 1-4 of paragraph 0014; lines 1-3 of paragraph 0015; line 1 of paragraph 0017 through line 10 of paragraph 0020; line 1 of paragraph 24 through line 15 of paragraph 0030; lines 1-6 of paragraph 0038; line 1 of paragraph 0055 through line 8 of paragraph 0056; line 1 of paragraph 0057 through line 3 of paragraph 0058; lines 20-31 of paragraph 0058; Figure 2); and

creating a negative hearing aid mold (lines 1-16 of paragraph 0010; line 1 of paragraph 0017 through line 4 of paragraph 0021; line 1 of paragraph 0027 through line 15 of paragraph 0030; lines 1-3 of paragraph 0033; line 1 of paragraph 0039 through line 4 of paragraph 0040; line 1 of paragraph 0043 through line 123 of paragraph 0047; lines 1-24 of paragraph 0050; lines 1-13 of paragraph 0051; lines 1-15 of paragraph 0056; line 1 of paragraph 0058 through line 17 of paragraph 0060; Figures 2 and 7) having an inside surface (lines 8-16 of paragraph 0010; lines 1-15 of paragraph 0030; lines 1-3 of paragraph 0044; lines 1-3 and lines 11-15 of paragraph 0046; lines 7-12 of paragraph 0051; lines 20-31 of paragraph 0058; Figures 1 and 8) with dimensions the same as the outside dimensions of the auditory

canal (lines 6-15 of paragraph 0010; lines 1-15 of paragraph 0030, lines 1-13 of paragraph 0051; lines 28-31 of paragraph 0058; Figure 2), with the negative hearing aid mold suitable for receipt of a soft solid (line 1 of paragraph 0010 through line 2 of paragraph 0011; lines 1-5 of paragraph 0018; line 1of paragraph 0021 through line 3 of paragraph 0022; lines 1-15 of paragraph 0030; lines 1-4 of paragraph 0040; lines 6-8 of paragraph 0043; lines 4 of paragraph 0044 through line 15 of paragraph 0045; lines 31-33 of paragraph 0058; line 1 paragraph 0059 through line 17 of paragraph 0060; Figures 2 and 8).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 2, 6, 7, 19, and 20 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Widmer et al. (U.S. Patent No. 6,540,045).

B. Whether claims 3-5 and 26 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Widmer et al. (U.S. Patent No. 6,540,045) in view of Rubbert et al. (U.S. Patent No. 7,027,642).

C. Whether claim 21 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Widmer et al. (U.S. Patent No. 6,540,045) in view of Jordan et al. (U.S. Patent No. 6,152,731).

VII. ARGUMENT

Each of the three grounds for rejection to be reviewed on appeal is based on the law of obviousness, derived from the following statute:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

As the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *See In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added in BPAI ruling). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21; *see also,* MPEP § 2144.03.

It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it

made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697; *see also,* MPEP § 2144.03.

A. Arguments against the rejection under § 103(a) as being obvious over Widmer et al. (U.S. Patent No. 6,540,445).

1. Arguments regarding claim 1.

Appellant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. The Widmer reference does not describe, teach, or render obvious each and every element and limitation of Appellant's independent claim 1. Although, as the Examiner points out in the Advisory Action, this is a rejection based on § 103 rather than § 102, all claimed elements must be suggested for an obviousness rejection to be maintained. As no secondary reference has been provided, Appellant also submits that the Examiner has not provided an articulated reasoning with some rational underpinning to explain why the differences between claim 1 and Widmer would have been obvious to one of ordinary skill in the art.

First, Appellant is unable to find in Widmer a method including "processing the outside auditory canal dimension data to generate outside mold data", as provided in claim 1. The Advisory Action of May 7, 2008 states:

> In the instant case, processing the data to form a desired mold – of whatever desired size – is simply believed to have been obvious over the disclosure of Widmer without a reference teaching the exact dimensions being used to make the mold. Ie, one of ordinary skill in this art would be able to pick respective dimension needed to make the mold the desired size.

With respect to the assertion that one of ordinary skill in the art could "pick respective dimensions needed to make the mold the desired size," the Appellant respectfully submits that "picking dimensions" is not the equivalent of "processing the outside auditory canal dimension data to generate outside mold data." In addition, even one of extraordinary skill in the art would not be likely to "pick"

dimensions carefully enough to allow creation of "a negative hearing aid mold having an inside surface with dimensions the same as the outside dimensions of the auditory canal," as stated in claim 1.

Second, Appellant is unable to find in Widmer a method including "creating a negative hearing aid mold having an inside surface with dimensions the same as the outside dimensions of the auditory canal, with the negative hearing aid mold suitable for receipt of a soft solid", as provided in claim 1. The Final Office Action of February 21, 2008 acknowledges on Page 2 that "Widmer et al does not explicitly teach making a hearing aid mold from the processed data." The Examiner has concluded that these elements are obvious over Widmer without an additional reference.

Page 3 of the Final Office Action states:

> Based on the disclosure of the prior art in Widmer et al, it is respectfully submitted that making a negative mold – instead of a shell – from the digital information would have been obvious modification to Widmer et al so that one could make the shell of materials different than those used to make the mold. Also, if it is known to make a product directly from digital data, it surely would have been obvious to make a mold from that data and then make the product from that mold. This kind of processing is notoriously well known in the art and performed regularly in order to tailor the materials used for the final product.

With respect to the assertion that making a negative mold instead of a shell would have been an obvious modification of Widner, the Appellant respectfully submits that Widmer teaches away from the use of molds. The background section of the Widmer reference, at column 1, lines 20-27, states:

> When manufacturing hearing aid shells today typically audiologists produce a model of the shape of the individual auditory canals, thereby taking a mold thereof, typically of silicon. This model is then sent to the hearing aid manufacturer who on the basis of this basis casts a hearing aid shell from a plastic material.

As Widmer points out, casting hearing aid shells from a positive physical mold is known. However, Widmer goes on to teach away from using a mold at column 1, lines 53-60:

> The above mentioned procedure is on one hand highly labor intensive and on the other hand the resulting hearing aid will mostly be less than optimal with respect to comfort of wear and space utilization. The material used in this conventional manufacturing furthermore necessitates a relatively thick wall of the in-ear hearing aid shell, thereby further and additionally reducing the space available for implementing the functional components.

As Widmer teaches away from the use of molds, one of ordinary skill in the art would not be inclined to modify Widmer's teachings to create a negative hearing aid mold according to Appellant's independent claim 1.

As Widmer does not appear to identify the desire to "make the shell of materials different than those used to make the mold," because Widmer does not use a mold, the Appellant respectfully submits that such an assertion could be based on hindsight bias. While the Appellant is well aware that *KSR* opposes a strict application of the teaching-suggestion-motivation test, Appellant is not urging such an application. Rather, Appellant merely points out that the logic used by the Examiner to support the obviousness rejection is based on a TSM style rationale, the basis of which appears in Appellant's specification rather than in the Widmer reference.

With respect to the assertion that if it is known to make a product directly from digital data, it would have been obvious to make a mold from that data and then make the product from that mold, the Appellant respectfully submits that, logically, adding an intermediate step to a process is not an obvious modification of the process. Such is particularly the case as Widmer teaches away from the use of molds. For example, Widmer appears to have as an objective the elimination of the above mentioned drawbacks with respect to the use of a mold by using an additive, built-up process, which is a manufacturing method that bypasses the step of using a mold, to directly fabricate hearing aids. (Column 1, lines 61-66).

Furthermore, the Appellant notes that the Examiner has relied on the assertion that it would have been obvious to make a negative mold from digital data, then make the product from the negative mold because it is known to make a product directly from digital data, without documentary evidence to support such assertion. Such an assertion, unsupported by substantial evidence, is insufficient to

sustain an obviousness rejection because such is not common knowledge in the art. Accordingly, the Examiner has not established a *prima facie* case of obviousness.

For the reasons provided above, Appellant respectfully submits that each and every element and limitation of independent claim 1, as previously presented, is not taught, described, or rendered obvious by the Widmer reference. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejections for independent claim 1, as well as the claims that depend therefrom.

2. Arguments regarding claims 2, 6, 7, 19, and 20.

Claims 2, 6, 7, 19, and 20 depend either directly or indirectly from independent claim 1. For the reasons set forth above, Appellant respectfully submits that claim 1 is in condition for allowance. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of dependent claims 2, 6, 7, 19, and 20.

B. Arguments against the rejection under § 103(a) as being obvious over Widmer et al. (U.S. Patent No. 6,540,445) in view of Rubbert et al. (U.S. Patent No. 7,027,642).

Claims 3-5 and 26 were rejected under 35 USC § 103(a) as being unpatentable over Widmer et al. (U.S. Patent No. 6,540,045) in view of Rubbert et al. (U.S. Patent No. 7,027,642) for reasons of record as set forth in paragraph 2, supra, and paragraph 5 of the previous action. Appellant respectfully traverses the rejections as follows.

Appellant submits that independent claim 26 is also in condition for allowance for at least the reasons stated above with respect to claim 1. That is, Widmer does not support a proper *prima facie* case of obviousness as Widmer, besides other things, does not describe or suggest all the elements recited in claim 26. Rubbert does not cure the deficiencies of Widmer. For example, Rubbert does not describe, teach, or suggest, independently or in combination with Widmer, processing the outside auditory canal dimension data to generate outside mold data and creating a negative hearing aid mold having an inside surface with dimensions

the same as the outside dimensions of the auditory canal, with the negative hearing aid mold suitable for receipt of a soft solid, as provided in claim 26.

Claims 3-5 are dependent on independent claim 1, which is in condition for allowance for at least the reasons stated above. That is, Widmer does not support a proper *prima facie* case of obviousness as Widmer, besides other things, does not describe or suggest all the elements and limitations recited in claim 1. Rubbert does not cure the deficiencies of Widmer. For example, Rubbert does not describe, teach, or suggest, independently or in combination with Widmer, processing the outside auditory canal dimension data to generate outside mold data and creating a negative hearing aid mold having an inside surface with dimensions the same as the outside dimensions of the auditory canal, with the negative hearing aid mold suitable for receipt of a soft solid, as provided in claim 1.

As such, Appellant respectfully submits that each and every element and limitation of claims 3-5 and 26 are not described, taught or rendered obvious by Rubbert and Widmer, either individually or in combination. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the 103(a) rejection of dependent claims 3-5 and independent claim 26.

C. Arguments against the rejection under § 103(a) as being obvious over Widmer et al. (U.S. Patent No. 6,540,445) in view of Jordan et al. (U.S. Patent No. 6,152,731).

Claim 21 was rejected under 35 USC § 103(a) as being unpatentable over Widmer et al. (U.S. Patent No. 6,540,045) in view of Jordan et al. (U.S. Patent No. 6,152,731) for reasons of record as set forth in paragraph 2, supra, and paragraph 6 of the previous action. Applicant respectfully traverses the rejections as follows.

Claim 21 is dependent on independent claim 1, which is in condition for allowance for at least the reasons stated above. That is, Widmer does not support a proper *prima facie* case of obviousness as Widmer, besides other things, does not describe or suggest all the elements recited in claim 1. Jordan does not cure the deficiencies of Widmer. For example, Jordan does not describe, teach, or suggest, independently or in combination with Widmer, processing the outside auditory

canal dimension data to generate outside mold data and creating a negative hearing aid mold having an inside surface with dimensions the same as the outside dimensions of the auditory canal, with the negative hearing aid mold suitable for receipt of a soft solid, as provided in claim 1.

As such, Applicant respectfully submits that each and every element and limitation of claim 21 is not taught or suggested by Jordan and Widmer, either individually or in combination. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 103(a) rejection of dependent claim 21.

The Examiner is invited to telephone Applicant's attorney, Sara J. Citrowske, at (612) 236-0123 with regard to this matter.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS Appeal Brief-Patents** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 26 day of June, 2008.

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6/26/08
Date:

VIII. CLAIMS APPENDIX

1. (Previously Presented) Method comprising:

processing auditory canal dimension measurement data representing dimensions of an auditory canal to generate outside auditory canal dimension data that represents outside dimensions of the auditory canal;

processing the outside auditory canal dimension data to generate outside mold data; and

creating a negative hearing aid mold having an inside surface with dimensions the same as the outside dimensions of the auditory canal, with the negative hearing aid mold suitable for receipt of a soft solid.

2. (Original) The method of claim 1 with processing the auditory canal dimension measurement data representing dimensions of the auditory canal comprising measuring the outside dimensions of an impression of the auditory canal to generate the outside auditory canal dimension data.

3. (Original) The method of claim 2 with measuring the outside dimensions of the impression of an auditory canal comprising measuring the outside dimensions of the impression of the auditory canal with a laser to generate laser measured auditory canal data.

4. (Original) The method of claim 2 with measuring the outside dimensions of the impression of an auditory canal comprising:

measuring the outside dimensions of the impression of the auditory canal with a laser to generate laser measured auditory canal data; and

generating point cloud/STL data from the laser measured auditory canal data.

5. (Original) The method of claim 2 further comprising analyzing the impression to generate auditory canal point cloud/STL data using a laser to measure

a plurality of surface positions on the impression to generate the auditory canal point cloud/STL data.

6. (Original) The method of claim 1 with processing the outside auditory canal dimension data to generate outside mold data comprising generating point cloud/STL data.

7. (Original) The method of claim 6 further comprising generating stereo lithography data from the point cloud/STL data.

8. (Withdrawn) The method of claim 1 with creating the negative hearing aid mold comprising creating a negative hearing aid mold from the outside mold data using stereo lithographic techniques with the negative hearing aid mold suitable for use as an outside mold for the construction of a soft solid hearing aid.

9. (Withdrawn) The method of claim 1 with creating the negative hearing aid mold comprising making an epoxy based hearing aid mold from the outside mold data using rapid prototyping such as stereo lithography.

10. (Withdrawn) The method of claim 1 with the creating the negative hearing aid mold comprising making an epoxy based hearing aid mold from the outside mold data using rapid prototyping such as stereo lithography with SLA Epoxy Resin Si-10.

11. (Withdrawn) The method of claim 1 with the creating the negative hearing aid mold comprising making an medical grade acrylonitrile butadiene styrene ABS based hearing aid mold from the outside mold data using rapid prototyping such as fused deposition modeling.

12. (Withdrawn) The method of claim 1 with the creating the negative hearing aid mold comprising making an powdered nylon hearing aid mold from the outside mold data using rapid prototyping such as laser sintering.

13. (Withdrawn) The method of claim 1 with the creating the negative hearing aid mold comprising making an powdered nylon hearing aid mold from the outside mold data using rapid prototyping such as Digital light processing.

14. (Withdrawn) The method of claim 1 with the creating the negative hearing aid mold comprising making an epoxy based hearing aid mold from the outside mold data using rapid prototyping such as stereo lithography with epoxy resin.

15. (Withdrawn) The method of claim 1 further comprising:
mounting the negative hearing aid mold on a faceplate; and
placing a soft solid in the negative hearing aid mold.

16. (Withdrawn) The method of claim 15 further comprising installing hearing aid electronics and transducers on the face plate before the negative hearing aid mold is mounted on the faceplate.

17. (Withdrawn) The method of claim 15 with placing the soft solid in the negative hearing aid mold comprising placing silicone in the negative hearing aid mold.

18. (Withdrawn) The method of claim 1 further comprising installing hearing aid transducers and electronics in the negative hearing aid mold.

19. (Original) The method of claim 1 with processing the auditory canal dimension measurement data comprising processing with a computer processor the auditory canal dimension measurement data representing dimensions of the auditory

canal to generate the outside auditory canal dimension data.

20. (Original) The method of claim 1 with processing the outside auditory canal dimension data comprises processing with a computer processor the outside auditory canal dimension data to generate outside mold data.

21. (Original) Method of claim 1 further comprising measuring auditory canal dimension measurement data representing dimensions of an auditory canal directly from the auditory canal to generate outside auditory canal dimension data that represents outside dimensions of the auditory canal.

22. (Withdrawn) Method of claim 1 with creating a negative hearing aid mold from the outside mold data using rapid prototyping further comprises creating the negative hearing aid mold from the outside mold data using rapid prototyping such as stereo lithography.

23. (Withdrawn) Method of claim 1 with creating a negative hearing aid mold from the outside mold data using rapid prototyping further comprises creating the negative hearing aid mold from the outside mold data using fused deposition modeling.

24. (Withdrawn) Method of claim 1 with creating a negative hearing aid mold from the outside mold data using rapid prototyping further comprises creating the negative hearing aid mold from the outside mold data using Digital light processing.

25. (Withdrawn) Method of claim 1 with creating a negative hearing aid mold from the outside mold data using rapid prototyping further comprises creating the negative hearing aid mold from the outside mold data using laser sintering.

26. (Previously Presented) A method for making a negative hearing aid mold comprising the steps of:

processing laser measured auditory canal dimension measurement data representing dimensions of an auditory canal to generate outside auditory canal dimension data that represents outside dimensions of the auditory canal, with the laser measured auditory canal dimension measurement data obtained with a laser measurement system;

processing the outside auditory canal dimension data to generate outside mold data; and

creating a negative hearing aid mold having an inside surface with dimensions the same as the outside dimensions of the auditory canal, with the negative hearing aid mold suitable for receipt of a soft solid.

IX. EVIDENCE APPENDIX

No evidence is submitted.

X. RELATED PROCEEDINGS APPENDIX

As there are no appeals or interferences known to Appellant's Representatives which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, there are no copies of decisions rendered by a court or the Board to submit.